DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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The Honorable Richard G. Lugar
United States Senate
Washington, D.C. 20510-1401

Dear Senator Lugar:

Thank you for the letter of June 4, 2002, on behalf of your constituent, Ms. Teresa LeCount of New Paris, Indiana, regarding the classification and safety of mercury amalgam dental fillings.

Dental amalgams, a mixture of silver, mercury, tin, and copper, have been used in dentistry for over 150 years. Controversy over the health effects from the use of these materials in dentistry has persisted for many years.

In January 1993, the United States Public Health Service (PHS) published a comprehensive scientific report on the safety and clinical utility of dental amalgam and the restorative materials commonly used in dentistry. The report, entitled, "Dental Amalgam: A Public Health Service Strategy for Research, Education and Regulation," acknowledged that amalgam fillings release small amounts of mercury vapor that the body can absorb and could cause allergic reactions in a few persons but that ". . . there is scant evidence that the health of the vast majority of people with amalgam is compromised." The PHS position on dental amalgams published in 1993 and updated in 1995 and 1997 is that "there exist no scientifically compelling reasons either to discontinue or to curtail the clinical use of dental amalgam or to recommend removal of existing amalgam fillings absent clear evidence of allergy or intolerance in individual patients."

PHS scientists analyzed approximately 60 peer-reviewed studies submitted to support three citizen petitions received by FDA after the 1993 report. They found that data in these studies did not support claims that individuals with dental amalgam restorations will experience adverse effects, except for rare allergic or hypersensitivity reactions.

The National Institutes of Health (NIH), the Centers for Disease Control and Prevention, and FDA have continued to work on the issue. NIH's National Institute of Dental Research has funded research related to improving the knowledge of dental amalgam safety and developing safe non-mercury alternatives. This includes epidemiological research, as well as clinical trials on dental amalgam use in children. These trials are ongoing and allow at least seven years of follow-up in order to detect possible subtle and long-range health effects.

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Dental amalgam also was the subject of a World Health Organization (WHO) Consultation in March 1997. The conclusion of the WHO Consultation was: "Dental amalgam restorations are considered safe, but components of amalgam and other dental restorative materials may, in rare instances, cause local side effects or allergic reactions. The small amount of mercury released from amalgam restorations, especially during placement and removal, has not been shown to cause any other adverse health effects." This conclusion mirrors the conclusions of the risk assessments done to date by PHS, the European Union, the National Board of Health and Welfare in Sweden, the New Zealand Ministry of Health, and Canada and the province of Quebec.

The use of dental amalgam in the United States is declining. Pediatric dentists in particular are tending to use resin (plastic), tooth-colored materials that are bonded to the tooth, may release fluoride, and are mercury free. There are other reasons for the decline as well, including the increasing use of sealant and community fluoridation, an expanding selection of fluoride-containing dental products, improved oral hygiene practices, and greater access to dental care.

For the foreseeable future, however, the population with still functional dental amalgam restorations will continue to be large. PHS will continue its strategy to gather data about any possible risks in the use of dental amalgams and other restorative products and to pursue aggressively new methods of dental treatment and oral health strategies. For updates on the safety of dental amalgams, visit our website at:
http://www.fda.gov/cdrh/consumer/amalgams.html.

Dental amalgams are Class II medical devices subject to Special Controls under the Federal Food, Drug, and Cosmetic (FD&C) Act. Dental amalgams marketed prior to passage of the Medical Device Amendments to the FD&C Act in 1976, and dental amalgams marketed since then but determined to be substantially equivalent to a preamendments device, have been allowed to be marketed without premarket clearance from FDA. New dental amalgams, determined to be not substantially equivalent to a preamendments device, first require premarket clearance before they can be marketed. All dental amalgams, however, must comply with all other regulatory requirements applicable to any Class II device.

In the Federal Register of February 20, 2002, FDA published a proposed rule that would uniformly regulate dental mercury, amalgam alloy, and pre-encapsulated dental amalgam in Class II. To reduce allergic reactions from restorative materials, FDA has proposed in labeling guidance that the product's labeling list ingredients in descending order of weight by percentage and include lot numbers, appropriate warnings and precautions, handling instructions, and expiration dating.

On July 17, 2002, FDA announced in the Federal Register the reopening for 60-days the comment period for the proposed rule. The comment period closes on September 17, 2002. Once we have reviewed and addressed comments to the proposed rules and guidance documents, FDA will issue final documents. We are forwarding this letter to FDA's docket for comments on the rule.

Thank you again for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,

Joan M. Eaton

for William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

cc: Dockets Management Branch (HFA-305)